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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,108	06/24/2003	Gary L. Breton	PATH03-14	2547

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,108

Applicant(s)

BRETON, GARY L.

Examiner

Shubo (Joe) Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-10, drawn to polynucleotides and vector and host cell containing same, classified in Class 536, subclass 23.1 and 24.1; Class 435, subclasses 320.1, and 325 and 419.
- II. Claim 17, drawn to polypeptides, classified in Class 530, subclass 300.
- III. Claims 11-13, drawn to vaccines comprising polynucleotides, classified in Class 436, subclass 500.
- IV. Claims 18-20, drawn to vaccines comprising polypeptides, classified in Class 436, subclass 500.
- V. Claims 14-16, drawn to methods of treatment using vaccine comprising DNA, classified in Class 424, subclass 184.1.
- VI. Claims 21-23, drawn to methods of treatment using vaccine comprising polypeptide, classified in Class 424, subclass 184.1.
- VII. Claim 24, drawn to method of detection of polynucleotides based on binding, classified in Class 435, subclass 6.
- VIII. Claims 25-28, drawn to computer readable medium containing polynucleotide sequences thereon, or a computer system or a method of use thereof, classified in Class 702, subclass 19.

The inventions of groups I-VIII are independent/distinct, each from the other because of the following reasons:

Inventions of group VIII and any of groups I-VII are unrelated. Inventions are unrelated

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if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case, the invention of group VIII is computer related, i.e. a computer readable medium or a computer system or a method of using thereof, whereas the inventions of groups I-VII are chemical substances or uses thereof. Clearly a computer readable medium or a computer system is not disclosed as capable of being used together with a chemical substance irregardless of what are contained in the computer readable medium or computer system. And clearly a computer readable medium or computer system has different modes of action, structure and function from a chemical substance.

Inventions of groups I-IV are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, polynucleotides, which are composed of purine and pyrimidine units, and polypeptides, which are composed of amino acids, are structurally distinct molecules. The polynucleotides in group I or III and the polypeptide in group II or IV do not overlap in scope, are not obvious variants, have different mode of actions, function and effect. The polynucleotide of group I and the vaccine of group III are mutually exclusive, not obvious variants and have different components and certainly different mode of actions, function and effect. Ditto for the polypeptide of group II and the vaccine of group IV.

Inventions of groups V, VI, and VII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually

exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of treating disease using DNA vaccine (V), using polypeptide vaccine (VI), and the method of detecting the presence of polynucleotides based on binding (VII) are mutually exclusive, not obvious variants and have different modes of actions, functions and effects.

The inventions of Groups I and VII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the process of the inventions of VII, i.e. detection of the presence of polynucleotides. Alternatively, the nucleic acids of Group I can be used in making recombinant polypeptides in vitro or in antisense technologies, e.g. inhibiting gene expression in vivo, which is a distinct usage of such nucleic acids.

The inventions of Groups III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polynucleotide vaccine of group III can be used in the process of group V, i.e. treatment of a disease, or it can be used in prevention of a disease, which is a materially different process because prevention occurs prior to the occurrence of a disease as opposed to treatment which is after the occurrence of the disease.

The inventions of Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the polypeptide vaccine of group IV can be used in the process of group VI, i.e. treatment of a disease, or it can be used in prevention of a disease, which is a materially different process because prevention occurs prior to the occurrence of a disease as opposed to treatment which is after the occurrence of the disease.

Because these inventions are independent/distinct for the reasons given above and have different classifications, they have acquired a separate status in the art, and are usually published separately in the literature. Thus, there would be a serious search burden if they were examined together. Therefore, restriction for examination purposes as indicated is proper.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143). Applicant is reminded that a fully responsive communication will comprise a proper election of a group and sequence as set forth above. Examination cannot proceed without a complete response.

This election of sequence is not a species election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

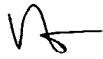
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general patent information available to the public. For all other customer support, please call the
USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.



Patent Examiner

John S. Brusca 1 December 2005
JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER